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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,543	01/17/2002	David E. Lam		7769

25225 7590 12/29/2005

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,543	LAM ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9 and 14-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9 and 14-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 4-9, 14-55 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 10-13-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

Examiner has withdrawn the benefit of prior US application 08/651,572 with filing date 5-22-1996. This is because Examiner has now found out that said above application which has matured in to US 5,789,228, issued on 8-4-1998 has no support for the claimed polynucleotide sequence SEQ ID NO:45 encoding the polypeptide with SEQ ID NO:46. The above prior application has only 6 sequences, out of which only SEQ ID NO:1 is the full length polynucleotide encoding the polypeptide with SEQ ID NO:2. Examiner has independently determined from his search, as well as from applicant's response filed on 10-13-05 that the polynucleotide with SEQ ID NO:1 in the above prior application is different from that of SEQ ID NO:45 claimed herein (see the sequence alignment provided by the applicant along with the response filed on 10-13-05). Applicant has in fact provided evidence that the SEQ ID NO:1 in the above prior application is only 44% identical to SEQ ID NO:45. There are no other full length polynucleotide sequences disclosed in the above application. Therefore, the benefit of priority has been withdrawn. The effective filing date for determination of prior art is now the filing date of the PCT application 5-22-1997.

Drawings

Examiner notes that applicants have filed a color photograph. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Objections

Claims 19 and 54 are objected to because of the following informalities: Claims 19 and 54 recite the phrase "at least" in tandem in line 3. Appropriate correction is required.

Claim 40 is objected to because of the following informalities: Claim 40 recites the phrase "a probe for identifying or isolated a nucleic acid" which appears to be grammatically improper. Appropriate correction is required.

Claims 27-28 are objected to because of the following informalities: Claims 27-28 recite the phrase "70%, 90% or 95% sequence identity an amino acid sequence.." which appears to be grammatically improper. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8, 53 and claims 9 and 14 depending therefrom are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 8 and 53 are simply drawn to "A host cell comprising ... nucleic acid having a sequence...". It is not clear from the claim that the host cell is an isolated host cell and therefore could read as a host cell still attached to a organism, and when considered broadly could read on a host cell attached to a human. Subject matter directed to transformation of cell attached to a human is considered non-statutory. Therefore claims 8, 53, 9 and 14 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter. Amending the claim to recite "An isolated host cell transformed with..." would overcome this rejection.

In response to he previous Office action, applicants have argued that the amendment to claim 53 overcomes the previously held rejection. While the previous rejection has been withdrawn the above new rejection is now directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 17, 19-23, 27-37, 40, 54 and claims 4, 6-9, 14-18, 24-26, 38-39, 41-53, 55 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2, 5, 17, 19-23, 27-37, 40, 54 recite the phrase "as set forth in SEQ ID NO:...". The metes and bounds of the phrase is not clear to the Examiner. It is not clear to the Examiner whether the phrase refers to the SEQ ID NO directly or whether the SEQ ID NO is a representative of the SEQ ID NO or the whether SEQ ID NO: is defined as "to stand for", to symbolize" etc. Examiner also notes that the sequence of the polypeptide /polynucleotide associated with the phrase need not be identical to said SEQ ID NO: if it is "set forth". Examiner suggests deletion of the phrase and referring the amino acid/nucleotide sequence directly for example "having the amino acid sequence SEQ D NO:46". Correction is required.

Claims 1, 17, 19-23, 27, 28, 32-37, 40-43 and claims 2, 4-9, 14-18, 24-26, 38-39, 44-53, 55 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 17, 19-23, 27, 28, 32-37, 40-43 recite phrases such as a) "...% sequence identity to **a** sequence set forth in SEQ ID NO.."; b) "has a sequence as set forth in ..." for example see claim 20; c) "an amino acid sequence as set forth in" for example see claim 31; d) "to **a** sequence as set forth in .." for example see claims 40-43, 54. These phrases are unclear to the Examiner because the claim as written does not make it explicit that the full length sequence is being claimed. Because the claims have language such as, for example "...% sequence identity to **a** sequence set forth in SEQ ID NO.."; it is not clear whether, the % sequence identity claimed is for the full length of said SEQ ID NO or for a fragment of said SEQ ID NO. Examiner suggests making a direct reference to the SEQ ID NO such as "having 99%

sequence identity to the amino acid/polynucleotide sequence SEQ ID NO.." to remove any ambiguity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-9, 14-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an endoglucanase having the amino acid sequence SEQ ID NO:46 encoded by a polynucleotide having the nucleotide sequence SEQ ID NO:45 vectors and host cells comprising said polynucleotide, does not reasonably provide enablement for any such polypeptide that has either 70%, 90%, 95%, or 97% sequence identity with SEQ ID NO:46 or polypeptides comprising 30 or 50 amino acids of a polypeptide that is 70% identical to SEQ ID NO:46 or cellulase polypeptides comprising 30 or 50 consecutive amino acids of SEQ ID NO:46 or a polynucleotide having a nucleotide sequence which is either 70%, 90%, 95%, 97% identical to SEQ ID NO:45 or a probe comprising 15, 25, 35, or 50 nucleotides of a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO:45, vectors and host cells comprising said polynucleotides and method of making said polypeptides. Claims are also not enabled for polypeptides comprising a sequence of SEQ ID NO:46 or polynucleotide comprising a nucleotide sequence of SEQ ID NO:45 (please note that Examiner has now interpreted claims drawn to polypeptides or polynucleotides with above language as claims drawn to variants, see the rejection under 112 2nd paragraph as well). The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-2, 4-9, 14-55 are so broad as to encompass any variants of SEQ ID NO:46 or any endoglucanase polypeptide that has either 70%, 90%, 95%, or 97% sequence identity with SEQ ID NO:46 or polypeptides comprising 30 or 50 amino acids of a polypeptide that is 70% identical to SEQ ID NO:46 or cellulase polypeptides comprising 30 or 50 consecutive amino acids of SEQ ID NO:46 or any variants of SEQ ID NO:45 or any polynucleotide having a nucleotide sequence which is either 70%, 90%, 95%, 97% identical to SEQ ID NO:45 or a probe comprising15, 25, 35, or 50 nucleotides of a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO:45, vectors and host cells comprising said polynucleotides and method of making said polypeptides.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and

guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only a single endoglucanase. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides and polynucleotides. The specification is limited to teaching the use of SEQ ID NO: 45 and 46 as a endoglucanase but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any endoglucanase polypeptide and polynucleotide encoding the same because the specification does not establish: (A) regions of the protein structure which may be modified without affecting its activity; (B) the general tolerance of endoglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including endoglucanases with an enormous number of amino acid modifications to SEQ ID NOS:46. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide having endoglucanase activity and the polynucleotides encoding the same is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicants have traversed the above rejection and continue to argue at length that the specification enables those skilled in the art at the time the invention was made to identify and make and use a genus of polypeptides having endoglucanse or cellulase activity and the nucleic acids that encode them to practice the claimed invention. In support of such an argument applicant earlier provided a Declaration by Dr. Short.

Applicant, while arguing that the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention, asserts that the references provided by the Examiner in support of the rejection are not specifically directed to the polypeptides and their variants claimed herein. In this round of arguments applicants maintain that the amount of time needed and difficulty in screening are not determinative of enablement undue experimentation if the experimentation is routine and that enablement is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive. Applicants maintain that experimentation is not considered undue, even if extensive, if it is routine or if the specification provides reasonable guidance regarding the direction of experimentation -- time and difficulty are not determinative of undue experimentation if the experimentation is routine (emphasis added). Applicants continue that there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" And that as set forth in *In re Wands*, these factors include, but are not limited to: The breadth of the claims; The nature of the invention; The state of the prior art; the level of one of ordinary skill; The level of predictability in the art; The amount of direction provided by the inventor; The existence of working examples; and, The quantity of experimentation needed to make or use the invention based on the content of the disclosure and aver that taking into consideration all of the evidence and argument presented to the Office the pending claims are sufficiently enabled. In response, Examiner agrees with applicants regarding their analysis of the Wands factors and would like to point out that said factors have been applied in the above rejection. While the experimentation may

involve routine techniques, in order to make variants as claimed, contrary to applicant's argument, Examiner maintains that one of ordinary skill in the art would be subject to undue experimentation. Examiner does acknowledge that the art has evolved to great heights, that it is now possible to set up high through-put assays to determine the activity of any given set of polypeptides. However, the crux of this enablement rejection is not the determination of the activity of the variant sequences. The crux of this enablement rejection is the lack of guidance for making the variant sequences, i.e., specific guidance as to which amino acid/nucleotide can be modified or replaced with which other amino acid/nucleotide. Examiner has rejected the claims because applicants have not provided specific guidance for making specific changes in the polypeptide/polynucleotide sequence without which those skilled in the art would be subject to undue experimentation.

Examiner reiterates that while it can be argued that methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan and even if such methods are routine, producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with specific guidance for the selection of specific amino acid or nucleotide residue that can be modified with which other amino acid or nucleotide and which among the extremely large number of variants have the claimed property (i.e., endoglucanase activity). Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if an extremely large amount of screening is required, the specification must provide a specific guidance with respect to the direction in which

the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without affecting its activity; (B) the general tolerance of endoglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Therefore the above rejection is maintained.

Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of polypeptides having endoglucanase activity and comprising 30 or 50 amino acids of a polypeptide that has 70% sequence identity to SEQ ID NO:46 or 30 to 50 amino acids of SEQ ID NO:46. The specification does not contain any disclosure of the structure of all such sequences included in the claimed genera. The genus of polypeptides claimed is a large variable genus with the potentiality of having different structures. Therefore, many structurally distinct polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus (i.e., that of SEQ ID NO:46) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of

a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by sequence or a recitation of structural features common to members of the genus, **which features constitute a substantial portion of the genus**. The recited structural feature of the genus (i.e., polypeptides having endoglucanase activity and comprising 30 or 50 amino acids of a polypeptide that has 70% sequence identity to SEQ ID NO:46 or polypeptides comprising 30 to 50 amino acids of SEQ ID NO:46) does not constitute a substantial portion of the genus as the remainder of the structure of such polypeptide having endoglucanase activity is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the above rejection, applicants have traversed. Again applicants argue at length that claims are indeed described. With respect to pending claims 27-30 directed to polypeptides having endoglucanase or cellulase activity comprising at least 30 or 50 amino acid residues of a polypeptide having at least 70%, 90% or 95% sequence identity to SEQ ID NO:46 or at least 30 or 50 amino acids of SEQ ID NO:46, applicants argue that these polypeptide share a common feature (limitation) in that they are drawn to fragments comprising at least 30 or 50 amino acid residues of an exemplary sequence of the invention, and it is this limitation that is the Office's primary concern. First, addressing the issue of whether claims 29 and 30 satisfy the

written description requirement, Applicants note that these claims are directed to polypeptides having exactly the same sequence as at least 30 or 50 residues of SEQ ID NO:46, where the claimed fragment has endoglucanase or cellulase activity. Applicants respectfully submit that the sequence of the claimed proteins that are subsequences of an exemplary sequence of the invention are described with reasonable clarity even though the limitations regarding the length of active subsequences (which at least 30 or 50 residue fragments of SEQ ID NO:46 have activity and fall within the scope of the claim) are not exactly described. Examiner respectfully disagrees with the above arguments. Applicant's claims are not simply limited to fragments or subsequences of SEQ ID NO:46 with activity, these claims are drawn to polypeptide sequences of any length, but comprising any 30 or 50 (irrespective of the fact whether they have activity or not) amino acids of SEQ ID NO:46. Therefore the only structure described for these polypeptides of any amino acid length is the fragment of 30 or 50 amino acids of SEQ ID NO:46. To conclude that the structure of said fragment describes the entire structure of the claimed polypeptide is highly erroneous.

Next applicants maintain that application does not need to describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that Applicants invented and had possession of the claimed subject matter and whether the specification clearly shows that Applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Applicants maintain that those factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional

characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Examiner respectfully disagrees with the applicant argument that evidence of possession can include a partial structure (see further below).

With respect to claims 29 and 30, applicants make a similar argument. Applicants note that claim 1, drawn to polypeptides having endoglucanase or cellulase activity having at least 70% sequence identity to SEQ ID N0:46, or encoded by a nucleic acid having at least 70% sequence identity to SEQ ID NO:45, is not subject to a written description rejection and that claims 27 and 28, as amended, are drawn to polypeptides comprising at least 30 or 50 amino acid residues, respectively, of a polypeptide having at least 70%, 90% or 95% sequence identity to an amino acid sequence as set forth in SEQ ID NO:46. Claim 1 has not been included in the rejection because the claim meets the full written description requirement, provides the full structure and the function of he polypeptide. However, claims 27-30 are short on structure and recite only the function. While the claims describe the structure of the polypeptide that is being compared with the claimed variant, the structure of the claimed variant itself is scant or not representative of the entire genus of the polypeptides claimed.

Thus as discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show

the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. **Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.** Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genera includes species which are widely variant in structure. The claimed genus encompasses polynucleotides/polypeptides with endoglucanase activity that are structurally diverse. As such, neither the description of the structure and function of SEQ ID NOS:45/46 nor the disclosure solely of functional features (or partial structure) present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus. Hence the rejection is maintained.

Claims 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising 15, 25, 35, or 50 contiguous nucleotides of a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO:45.

The specification does not contain any disclosure of the function of all DNA sequences that are encompassed by the claim. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the above rejection, applicants maintain that the above claims are described. However, Examiner respectfully disagrees. This is because, claims continue to be drawn to probes "comprising" set number of nucleotides. While it is acknowledged that the probes (of set length as 15, 30 nucleotides etc.) hybridize to SEQ ID NO:45, applicants have not provided the structure or the function of the nucleotides comprising the probes. It must be noted here that the use of "comprising" language leads those skilled in the art to conclude that the so called "probes" comprise sequences that may or may not hybridize to SEQ ID NO:45. And it is the structure and function of such sequences that applicants have not described. Hence the above rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-9, 14-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Bylina(a) et al. (US 6368844, 4-9-2002) or Bylina(b) et al. (US 2002/0155550 A1, 10-24-02, priority date 12-6-1996) or Short et al. (US 2002/0078397 A1, 4-24-03). This rejection is based upon the public availability of a printed publications/patent. Claims 1-2, 4-9, 14-55 of the instant application are drawn to a recombinant polynucleotide with SEQ ID NO:45 encoding an endoglucanase or cellulase enzyme having an amino acid sequence SEQ ID NO:46, several types of variants of the same, vectors and host cells comprising said polynucleotides, and methods of using said polynucleotide and polypeptide in various processes. All three of the above references having an effective priority date that precedes the filing date of the instant application disclose polynucleotide which is 100% identical to SEQ ID NO:45 encoding a polypeptide that is 100% identical to SEQ ID NO:46 (see sequence alignments provided with the Office action dated) and all the related methods of using them, thereby anticipating claims 1-2, 4-9, 14-55 as written.

In response to the above rejection in one of the previous Office actions, applicants had traversed and argued that the instant application claims the benefit of priority to the filing date of application 08/651,572 which is 5-22-1996. However, by applicant's own submission the

polynucleotide claimed in the above application is only 46% identical to SEQ ID NO:45 claimed herein and therefore for all practical purposes, the instant application has no support for SEQ ID NO:45 in the above application. Therefore, Examiner has withdrawn the benefit of said priority date and instituted the above rejections as before.

Double Patenting

Examiner has withdrawn the previous rejection of claim 36 under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of prior U.S. Patent No. 5,789,228 (application No. 08/651,572) in view of the evidence provided by the applicant that the sequence claimed in the above patent and SEQ ID NO: 45 are entirely different. However, Examiner also notes that applicants had indeed claimed the filing date of the application of the above patent for priority benefit. Now that applicant has clearly shown that the two polynucleotides are different and since no other full length polynucleotide sequence is disclosed in the patent, Examiner has determined that the instant application lacks support for SEQ ID NO:45 in the above patent application and therefore has not granted the benefit of priority date. The effective filing date i.e., 5-22-97 of the parent PCT application is the date considered for priority purposes of the instant application.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of

this application or proceeding should be directed to the receptionist whose telephone number is

571-272-1600.

Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

December 22, 2005